Technological Interventions in Fabrication of Prosthetic Sockets using Additive Manufacturing

A brief outline of the proposed research to be carried out

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Summary

Amputation is a major health burden on families, society, and medical services as well. It had been estimated that there are roughly 0.62 amputees in India per thousand populations. This translates to one million individuals with amputations in the country. India is a country where disabled people don't get proper treatment due to the high price of the prosthesis. Amputation in India is looked down upon as a mark of social outcast and amputees are looked upon as a liability. Under a lack of psychological consultancy, the amputees start losing their self-confidence. A prosthetic is a device that substitutes a lost body part. The prosthetic socket, the mechanical interface between an amputated residual limb and an external prosthesis, is a critical element for successful rehabilitation. This socket must be custom designed to provide comfort, appropriate load transmission, and efficient movement control and allowing it to be as naturally fitting as possible. Conventional prosthetic socket technology is derived using a non-quantitative, artisan methodology which involves complicated, time-consuming process and persons using these sockets often experience discomfort. As a resolution to this difficulty focus of this research is to improve the process for the manufacturing of comfortable prosthetic sockets using digital design involving CAD/CAM methodology, Additive Manufacturing (AM) technologies. There by to make prosthetic sockets widely available, easily accessible, cost-efficient, highly customized to a user for comfort, and better at adjusting and fitting to a growing body.

In this research, we propose a digital socket production workflow comprising the following steps:

1) Assessment of biomechanics of residual limb.

2) CAD modeling of the socket interface.

3) AM fabrication of a socket based upon above 1-2.

Proposed work will allow all communities to more easily access prosthetics and will have a crucial impact in bringing the amputees into mainstream life where they no longer will have to seek help for simple day to day activities.

1. Problem Identification

Medical prosthetics have been evolving since they were first reportedly used 3500 years ago. Wood and iron have been replaced by much stronger and lighter polymers and composites. With the advent of technology, the need for more ergonomic and dynamic designs that allow greater functionality has aroused [1-2]. The technology incorporated into prosthetics has also evolved, however, walking into a prosthetist's office one can easily find out the craftsmanship and expertise that goes into each patient's individual prosthetic. Despite the advancements in technology, traditional techniques are being used by hit and trial method so that patients prosthetic fit just right.

A survey in 1981 [3], revealed that approximately half a million people were amputees. It was observed that number of people with no prostheses was increasing by 17000 annually. In 2014, it was observed that 30 million people in the world were in need of prosthetic and orthotic devices [4,6]. In India alone, an estimation of 230,000 patients were in need of prosthetic care [7]. In the present scenario, approximately 10 million Indians live with movement impairment [8]. As per the statistical profile of disabled persons in India [9], 2.2% of the general population is disabled out of which 20% have movement disability.

According to the World Health Organization report, only 10% of the disabled people have access to assistive products [10]. Several studies [11-12], show that access to assistive devices is an important factor to improve the quality of life (QOL) of disabled people. Limb assistive devices help in mobility and a positive correlation was observed between mobility and QOL [13]. There are NGOs like Hardayal Viklang Sewa Kendra, Mahavir Seva Sadan, Jyot charitable trust, Bhagwan Mahaveer Viklang Sahayata Samiti, Mukti M.S.Dadha Foundation which provide prosthetics for people with movement impairment [14–18]. A field study was undertaken at Baghwan Mahaveer Viklanag Sewa Samiti (Jaipur foot organization), Jaipur and Hardayal Viklang Seva Kendra, Agra. Baghwan Mahaveer Viklanag Sewa Samiti was established in 1975 and treats approximately 10000 amputees every year. Hardayal Viklang Seva Kendra was established in 1996 and treats approximately 1200 amputees every year. The process of prosthetic manufacturing at these centers was similar to the traditional methods which will be discussed in

section 3.2. Interaction with the prosthetists and the patients revealed the problems faced during manufacturing and while using the traditionally manufactured sockets.

The demand for more effortless and naturally moving limbs is arising day by day and the manufacturing processes, technologies are evolving to meet the requirements. Emphasis is being laid on loading, stress and strain of prosthetic socket to enable the end user to replicate the functionality of their lost limb. A major problem in developing sockets is to meet the degree of personalization. Every individual has different characteristics of residual limb which makes the need for personalization high. According to the Zion market research report [19], the artificial limbs market in 2018 was valued at USD 1970 million is expected to reach USD 2758 million by 2024.

Apart from road accidents, there could be several medical reasons like gangrene, diabetes mellitus, PVD, wound infection, wound dehiscence and wound debridement and so on for loss of limb [20]. In a study by Gandla, Caren and Erel at Manglore, India for a period of 2 years, showed that 82% limbs were amputated for diabetic foot complications and 14% limbs for vascular etiology, 3% due to trauma and 1% due to other causes like tumors [20]. One of the main reasons for amputation is medical complications due to diabetes. For such patients it is essential that prosthetics must be made lightweight and durable to keep patients safe and comfortable. Care needs to be taken while designing the prosthetic socket as it is the point of contact between the prosthetic and residual limb. It is observed that improper designs can cause injuries due to continuous rupture between the skin and prosthetic and also due to the friction on skin. [21].

Researchers are trying to manufacture prosthetics using Additive Manufacturing (AM) to address the design issues discussed above. The sample prosthetic fabricated using AM has been tested for mechanical properties. But durability for long-term usage and feedback from patient after using the prosthetic are not being considered while designing and fabricating the prosthetic. Fatigue and safety of the devices is not evaluated for different use cases. New prosthetics must be designed and fabricated, if the size of the residual limb changes with time. An analysis of the existing materials may also be done to improve the durability, limited material strength, comfort and cosmetic appearance of the device. [22,24]

Production of prosthetic using AM involves high initial equipment cost, huge fabrication time, high material costs and uneconomic throughput [23]. These form the barriers for commercialization and to mass produce prosthetics using AM. Despite the technological advances in enhancement of socket/limb interfaces, prosthesis users still suffer from problems related to the high and repetitive loading of the limb while walking. Hence, there is a need for investigation on technological interventions in fabrication of prosthetic sockets using additive manufacturing (AM). The aim of this research is to understand principles and processes of AM technologies, current research and future advances in manufacturing of prosthesis and to build a viable solution.

2. Suggested solutions and alternatives

Considering the above mentioned challenges, the below may be viable solutions to them.

- A flexible socket and inner liner that can provide comfortable conditions for patients to prevent injuries caused due to friction between socket and residual limb.
- Performing durability test and considering feedback from patients while designing and fabricating the prosthetic will improve the quality.
- Quality control and testing of mechanical properties need to be exercised while designing the prosthetic to evaluate mechanical strength, long term durability, fatigue and safety.
- Better designs can be evolved through the use of techniques such as topology optimization and sparse structure which meet the quality requirement.
- New materials have to be investigated, to identify a material that can be used to fabricate a flexible prosthetic that would reshape as per the size of the residual limb and is lightweight.
- Creation of functional 3D printer that is low cost, fast and uses low cost materials to produce prosthetic sockets may be investigated.
- A clinical and design interface for AM needs to be developed to teach medical professionals to use and apply this technology to create prosthetics for individuals with amputations.

In this research focus is laid on development and application of AM for prosthetics sockets and the objectives are formulated accordingly.

3. Introduction and Literature Review

In this section, we discuss the existing prosthetic systems, different materials and approaches used to manufacture artificial limbs.

3.1 Limb prosthetic systems overview

Broadly there are three categories of the upper & lower limb prosthetics: passive, semi active and active and can be seen in fig. 1 & 2

Figure 1: (a) Passive Prosthesis (Aqualine From Ottoback), (b) Semi Active Prosthesis (C-Leg from Ottoback), (c) Active prosthesis (Triton from Ottoback). [25]

(a) (b) (c)

Figure 2: (a) Passive Prosthesis (Simple silicon cover Ottoback), (b) Semi Active Prosthesis (MyoFacil from Ottoback), (c) Active prosthesis (Michelangelo from Ottoback). [25]

Passive prosthesis is low cost device that offer basic functionality. They are fixed structures and act like spring and damper. [26]. In Semi active prostheses, microprocessors technology is used for instantaneous reaction of altering situations but is limited only to generate resisting forces. These are costlier than passive prostheses [27]. Active or powered prostheses are highly complex systems which use motors to provide external power. As a consequence, they have ability to act. They offer greater performance and functionality [28].

In general, the lower limb prosthetics comprises of Socket, Shank and Foot and Ankle assembly and upper limb prosthetics comprises of hand, wrist, and socket as shown in figure 3.

Figure 3: Components Lower and upper Limb Prosthetic [29]

Socket is the most important of all the components as it comes in contact with the residual limb. The shape of the socket differs from patient to patient. Proper fit and comfort are the main challenges in designing the socket. The socket is not mass produced as it is dependent on the size of the residual limb. There are two different processes to produce socket – mechanical and AM based. An overview of these socket manufacturing processes is given in the next subsection.

3.2 Conventional manufacturing processes of prosthetics sockets

In Conventional Method, the process starts with wrapping of plaster and glass fiber on residual limb to get its shape and geometry in the form of a cast. Then the prosthetics locate pressure points and build up or

remove material to make a note of the size. The plaster is removed and filled up with the slurry. After the slurry is settled, the glass fiber cast is destroyed to obtain positive mold which contains geometry of residual limb. Then high-density polyethylene (HDPE) or any other polymer tube is heated and placed over the positive mold to obtain the desired shape of the limb. Once the limb is formed the mold is removed and the prosthetic is trimmed and finished. Straps and foot ankle assembly are attached to the prosthetic formed before testing it on patient. [30].The process is shown in the figure 4.

This conventional method is widely used but the following limitations are observed [23,24] :

- A lot of manual processes are involved from creation of mold to the final testing phase which makes the conventional method labor intensive.
- To obtain the size of the limb, the patient's residual limb is wrapped with plaster, which may cause discomfort to them.
- The patient needs to visit the facility multiple times to obtain the prosthetic
- Process is dependent on well experienced technician to locate pressure points.
- The method is less precise and accurate due to involvement of multiple processes
- A lot of wastage like glass fiber and molds are generated which are not re-usable directly.
- It's a kind of hit and trial process and fitting is a big problem, therefore, the prosthetic needs to be cushioned for better fitting.
- Average life span of prosthetic is six months. For a given patient, every six months the whole process needs to be repeated to create a new prosthetic.
- Low strength and durability

The above limitations can be overcome to an extent by the usage of AM for manufacturing sockets which is discussed in next section.

(a) (b) (c)

Figure 5: Limitations of conventional method (a) Lot of wastage (b) Multiple visits (c) Manual Process

(a) (b)

(c) (d)

(e)

(f)

(g)

Figure 5: (a) Wrapping of Plaster on residual limb and locating pressure points (b) Pouring Slurry in the Plaster mould (c) Breaking the plaster mould to get positive mould (d) Forming of Heated HDPV on positive mould (e) Removal of cooled down HDPV Socket (f) Final Prosthetic limb after attaching straps & Foot Ankle assembly (g) Testing on patients. [17]

4.3 Additive Manufacturing

Additive manufacturing (AM) converts CAD model into a physical object through layer by layer addition of material [31]. AM is disrupting the traditional machining processes in a way similar to the disruption caused by steam powered engines, electrical machines and electronics in the first, second and third industrial revolutions, respectively. It has become one of the nine pillars of fourth industrial revolution (Industry 4.0) [32].

AM in its early days was known as rapid prototyping. Dr. Hideo Kodama, from Nagoya municipal industrial research was the first to give the theory of layer by layer manufacturing and conceptualize the process of stereolithography in the 1980s but couldn't file a patent [33]. Charles W. Hull printed a teacup using stereolithography method on 9th March 1983 [34]. Thus, 9th March 1983 marked the beginning of practical additive manufacturing. AM is also referred by other names like 3D printing and free form fabrication. AM is continuously evolving and is projected to make deepest impact in many areas like automobiles, aerospace, medical, and so on.

Commercialization of AM started in 1987 when Charles W. Hull co-founded 3D systems and released SLA-1 (SLA stands for stereolithography apparatus). This is based on laser-induced photo-polymerization process wherein a UV laser beam is rastered on a vat of photo-polymer resin. At the same time, solid object ultraviolet plotter (SOUP) by NTT data CMET, solid creation system (SCS) by Sony/D-MEC and stereolithography-based system by electro optical system (EOS) and quadrax were commercialized [35].

Early 90's shaped the landscape of additive manufacturing by introduction of five crucial technologies mentioned below: -

- Fused deposition modeling (FDM) from Stratasys
- Solid ground curing (SGC) from Cubital
- Laminated object manufacturing LOM) from Helisys
- Selective laser sintering (SLS) from DTM

Using the above technologies, the shaping of material takes place in the formation of elements that make up the required part. The elements could be in the form of voxels, filaments or layers and are shaped in

computer automated environments. The fabrication is accomplished using different materials like metallic, polymeric, ceramic, composite, and biological [35].

Among the various types of 3D printing, fused filament fabrication (FFF) has been recognized as the cheapest and the most widely adopted prototyping technology. In this a thermoplastic filament is heated to melt, then extruded from the nozzle and deposited layer by layer on a support platform. A FFF setup can be seen figure 6.

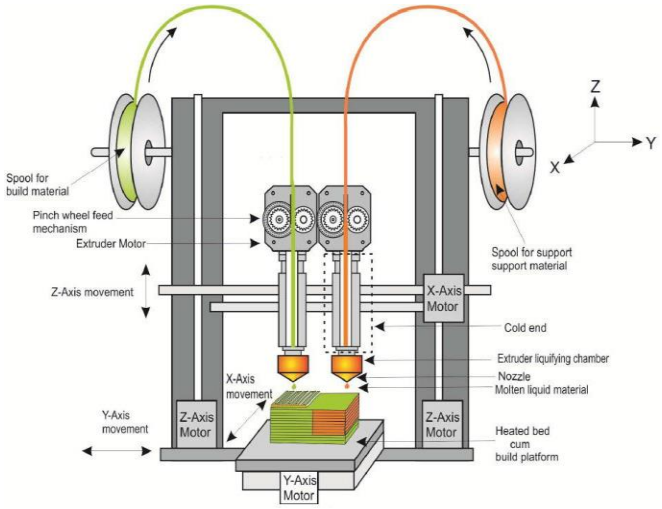

Figure 6: Fused Filament Fabrication

There are several advantages that AM provides over traditional manufacturing process. Some of them being [36]:

- High degrees of customization and personalization with little impact on manufacturing complexity.
- In low volume production environment, material waste, time, cost and inventory are significantly reduced and optimized.
- Fabrication of geometrically complex, compositionally heterogeneous, and individualized components is possible.
- Significant reduction in cost and timing of prototyping.

AM offers several applications ranging across broad areas such as lightweight machines, architectural modeling, medical applications, improving the manufacturing of fuel cells, for hobbyist and artistic

artifacts. AM helps in manufacturing objects that require high customization and geometric complexity. Articles for the home, sports equipment, prototypes for the validation of engineering processes, prosthetics, and surgical implants, turbine blades with high mechanical and thermal performances, building prototypes and so on are produced using AM.[37]. In the below sections, AM techniques for socket designing and materials used are discussed.

4.4 Additive manufacturing of prosthetic sockets

The limitation of conventional manufacturing process mentioned in above section creates need for alternative methods and additive manufacturing can be a viable solution.

AM offers the following advantages over the conventional method[37]:

Ease of Use and Comfort:

Traditional prosthetics limbs are known to be cumbersome due to socket discomfort. AM produced prosthetics are more customizable to users and are therefore farther superior comfort-wise.

Time, Speed and Quickness:

While it can take weeks to months to produce and calibrate a traditional prosthetic, it takes a minimum of one day to produce prosthetic via AM, making them more accessible.

Customization:

AM enables users to create specific shapes and sizes thereby allowing producing highly customizable prosthetic socket. AM also allows for the manufacturing of prosthetics that can be designed for various purposes and activities.

Versatility:

As we grow our body changes, prosthetics become obsolete and must be replaced. Replacing the prosthetic limb to keep pace with the rate of growth until the physically unique person reaches

maturity can be a pretty expensive process. Currently, researchers are working towards expandable prosthetics that will progress as the user's body changes over time.

Accessibility:

The Advent of AM process is making it easier to create different kinds of customizable and quality prosthetics that could impact countless lives.

An outline of the proposed procedure for production of prosthetic sockets using AM involves following steps[23]. The detailed procedure is mentioned in the flowchart in figure 7.

1. Use 3D scanning technologies to directly scan the residual limb or the negative mould created using conventional method. In certain cases, data may also be obtained through MRI scans.
2. Data collected through scanning process is converted to solid positive CAD model of residual limb. CAD software is used to make necessary modifications like locating pressure points etc are performed and final CAD model of the prosthetic socket is developed.
3. The CAD model is converted to AM formats like stl, obj, so on and imported into proprietary slicing software of printer to be used. Then G-codes are generated through slicing software and sent to 3D printer for fabrication.
4. After printing, the prosthetic may be polished, trimmed, and cushioned if necessary.

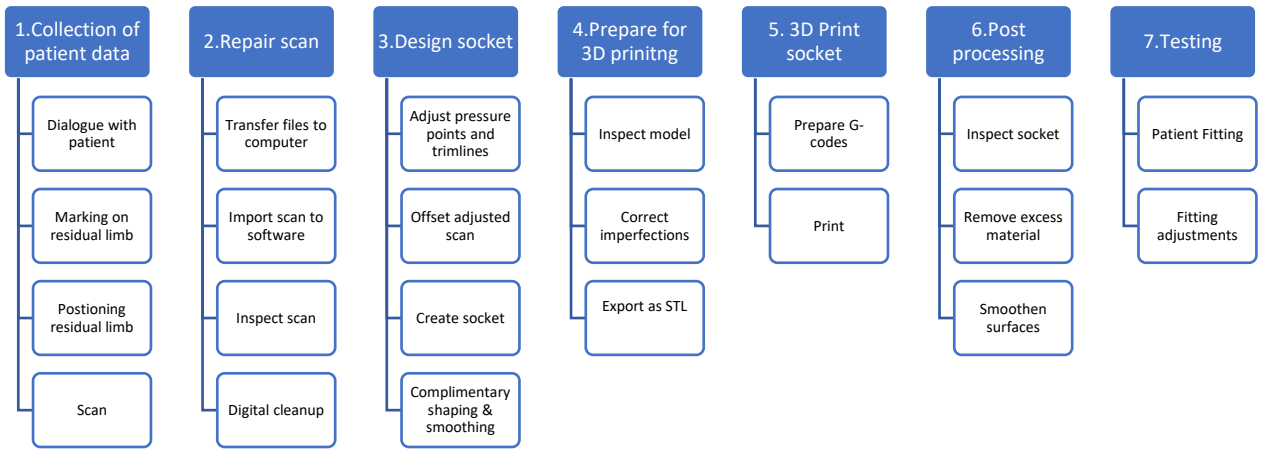

Figure 7: A general procedure of Prosthetic Socket manufacturing using AM

The research conducted to develop prosthetic socket using AM over the past ten years is summarized in Table 1.

Table 1: Summary of Research in Prosthetic Socket Fabrication using AM

Author and Date	Title	AM process	Material
Hsu et al., 2008 [38]	The Application of Rapid Prototyping for the Design and Manufacturing of Transtibial Prosthetic Socket	Fused Deposition Modeling	Polycarbonate
Hsu et al., 2010 [39]	The Development of a Rapid Prototyping Prosthetic Socket Coated with a Resin Layer for Transtibial Amputees	Fused Deposition Modeling	Polycarbonate coated with unsaturated polyester resin
Crawford, Montgomery, & Vaughan, 2010 [40]	Design of an actively actuated prosthetic socket	Selective Laser Sintering	Nylon 11 and Nylon 12
Sengeh & Herr, 2013 [41]	A Variable-Impedance Prosthetic Socket for a Transtibial Amputee Designed from Magnetic Resonance Imaging Data	Poly Jet	Vero White plus & Tango black Plus
Webber & Davis, 2015 [42]	Design of a novel prosthetic socket: Assessment of the thermal performance	Fused Deposition Modeling	Vero White plus
Comotti, Regazzoni, Rizzi, & Vitali, 2015 [43]	Multi-material design and 3D printing method of lower limb prosthetic sockets	Fused Deposition Modeling	Polylactic acid (PLA), Acrylonitrile butadiene styrene (ABS),
Nayak, Singh, Chaudhary, & Tripathi, 2016 [44]	A Novel Approach For Customized Prosthetic Socket Design	Fused Deposition Modeling	Acrylonitrile butadiene styrene (ABS),

Using AM, the prosthetic socket can be designed as per the requirement of the patient. An example of such designs can be seen in fig 6. Webber and Davis [42] modified the socket and incorporated helical cooling channel within the socket wall for maintaining normal thermal environment around the residual limb so that sweat doesn't form around the residual limb. Sengeh and Herr [41] developed a variable impedance prosthetic socket by incorporating compliant features to achieve lower interface peak pressures over bony protuberances. Comotti et al. [43] used multi materials for hard and soft areas of the prosthetic

to increase comfort for the patients. PLA is used for hard areas and rubber like material is used for soft areas where residual limb comes in contact with the socket. Different materials used for production of sockets are discussed in the next subsection.

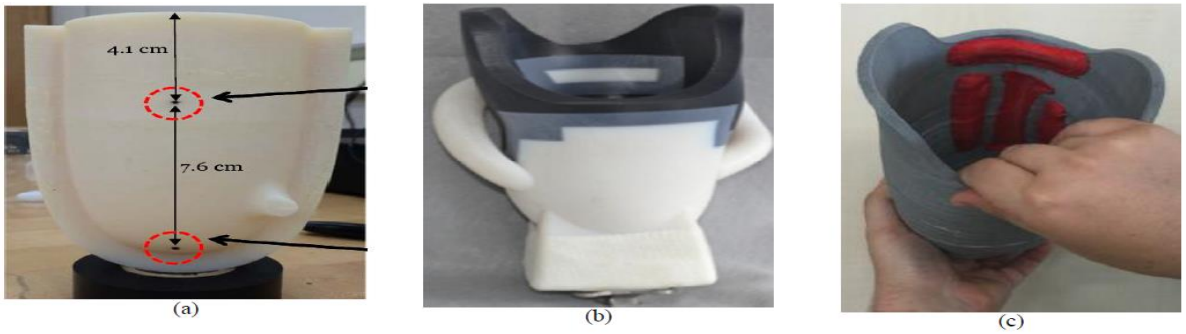

Figure 6: Designs of Prosthetics Sockets fabricated using AM by: (a) Webber and Davis [42] (b) Sengeh and Herr [41] (c) Comotti et al.[43]

Based on the above-mentioned comprehensive study, certain avenues for research have been identified, which are mentioned below:

- Need for better quality control and testing of mechanical properties of the prosthetic to evaluate fatigue and safety of the device in different use cases
- Evolution of better designs through use of techniques such as topology optimization and sparse structure which meet the quality requirement.
- Analysis of materials in the context of durability, limited material strength, comfort and cosmetic appearance.
- Need for comprehensive framework for AM of prosthetic sockets

4.5 Materials for manufacturing prosthetic sockets

The type of material used for manufacturing plays a crucial role as it decides the strength, weight, manufacturability, cost and durability of the socket [45]. Materials also play a crucial role in providing comfort, preventing epidermis damage such as irritation, breakdown and infection to the patient [21].

Ahmed et al. [46] analyzed the common materials used in fabrication of prosthetic socket using conventional method such as high-density polyethylene (HDPE), polypropylene (PP), polyvinyl chloride (PVC), polytetrafluoroethylene (PTFE) by using finite element analysis (FEM) and found that PVC shows the best performance while PTFE shows poor performance in the terms of stress, strain and safety factor. Sankaran et al. [21] summarized that natural fiber reinforced bio-composite material with the composition of glass and nylon fiber produces high young's modulus and tensile strength and also reduces epidermis sores.

Materials used by various researchers for AM of prosthetic socket are summarized in Table-1. Common materials used are PLA, ABS, PC, and Nylon. In context with AM, further research is needed to investigate methods to increase the physical and chemical properties of the material, increase durability and reduce the cost of the prosthetic. The role of nanocomposites in manufacturing of prosthetic sockets still needs to be investigated.

5. Methodology and Work Plan

1. Literature survey and analysis of the latest advancements in the design, manufacturing, and testing of prosthetic sockets.
2. Interviewing number of disabled people who uses prosthetics in Agra and Jaipur in order to get information on challenges that they are experiencing.
3. Visiting medical camps at NGOs like Hardayal Viklang Kendra and Baghwan Mahveer Viklang Seva Samiti (Jaipur Foot Org.) in order to identify cases.
4. Development of experimental test bench for personalized prosthetic sockets fabricated using AM.
5. Development of personalized prosthetic socket for different patients.
6. Analysis of multiple materials for manufacturing of prosthetic sockets.
7. Mechanical characterization and strength co-relationship of different lightweight/ nanocomposites/ fiber reinforced materials for AM of prosthetic sockets.
8. Bending Strength Test and Evaluation of Prosthetic Sockets Fabricated by Additive

Manufacturing.

9. Testing of developed prosthetic sockets for various use cases for pressure relief to increase socket comfort for amputees.
10. Clinical evaluation of prosthetic sockets manufactured by Additive Manufacturing.

6. Objectives

1. Design and fabrication of a comfortable (far superior, comfort-wise), accessible, versatile and affordable prosthetic socket using AM which meets the requirement of patients with emphasis on diabetic patients.
2. Working towards development of expandable/flexible prosthetics that will adapt to size, as per the changes in user's body over time.
3. To develop accessible novel comprehensive framework and pilot-scale demonstration of improved process for fabricating improved prosthetic sockets using AM in rural areas with Elimination of uncertainty.

7. Research Outcome

The proposed work shall bring rehabilitation possibilities to people who haven't had access to the prosthesis. This will be a step forward to restore normalcy in their lives, helping them to return to the usual routine, mainstream lifestyle and restoring their declining self-worth. The outcome would also garner faith from the general public being an Indian product as customer complaints can be locally handled and addressed. In proposed research technicians shall visit remote areas, conduct digital scans on-site using a handheld scanning device and bring in the digital 3D model of the limb. Then Prosthetics will be produced using the scanned model and will be sent to the patient. This will prevent the amputees from hauling around a facility or NGO far away from their place of stay under a lot of discomfort to themself and guardians. Funding for proposed research shall be tried from various agencies of Government of India as the proposal comes under the MAKE IN INDIA campaign and the research outcome is expected to be encouraged by Government as it would be a definite aid in reaching out to a growing population of amputees.

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